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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,413	03/30/2001	Shigeru Yamamoto	Q63731	8678

7590 05/18/2005
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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/806,413	Applicant(s) YAMAMOTO ET AL.	
	Examiner David J. Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,11,13,14,22,24 and 26 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 4 and 22 is/are allowed.
 6) ☒ Claim(s) 1,2,11,13,14,24 and 26 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/8/2005 has been entered.

[2] Claims 1-2, 4, 11, 13-14, 22, 24, and 26 are pending in the application.

[3] Applicants' amendment to the claims, filed 3/8/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[4] Receipt of a declaration filed under 37 CFR 1.132 (the "Tsuruhami Declaration"), filed 3/8/2005, is acknowledged.

[5] Receipt of an information disclosure statement (IDS), filed 3/8/2005, is acknowledged.

[6] Applicants' arguments filed 3/8/2005 have been fully considered and are deemed to be persuasive to overcome some of the objections and/or rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[7] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim for Priority

[8] Applicants' claim for foreign priority under 35 USC § 119(a)-(d) to Japanese application 10/294675, filed 9/30/1998, is acknowledged. A certified copy of the foreign priority document has been filed in the instant application on 3/30/2001.

Information Disclosure Statement

[9] With the exception of Hoesel et al., all references cited in the information disclosure statement (IDS) filed 3/8/2005 have been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

[10] The reference of Hoesel et al. has not been considered as it is in a foreign language and there is no statement of relevance for the document in accordance with 37 CFR 1.97(a)(3)(i).

[11] If the examiner has inadvertently overlooked an IDS that has previously been filed in the instant application, applicants' cooperation is requested in alerting the examiner to this IDS in the response to this Office action.

Specification/Informalities

[12] A substitute paper copy of the sequence listing has been filed in the instant application on 7/18/2001. However, the examiner can find no statement by directing entry of this substitute paper copy of the sequence listing into the specification.

Applicants are requested to provide such a statement.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[13] The rejection of claims 24 and 26 under 35 U.S.C. 112, second paragraph, (¶ [6] of the Office action mailed 12/10/2004) is withdrawn in view of the amendment to the claims.

[14] Claims 1-2, 11, 13-14, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (claim(s) 2 dependent therefrom), 11 (claim(s) 13-14 dependent therefrom), 24, and 26 are indefinite in the recitation of “naturally-occurring polypeptide.” MPEP 2173.02 states, “[i]f the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate.” In this case, it is unclear as to the physical and/or chemical characteristics that distinguish a polypeptide that is “naturally-occurring” from a non-naturally-occurring polypeptide. In other words, how does a skilled artisan determine whether a polypeptide, which otherwise satisfies all of the recited limitations of the claims, is “naturally-occurring” or non-naturally-occurring. For example, if a polypeptide that has an amino acid sequence that is identical to an endogenous polypeptide is recombinantly produced using a microorganism as recited in claim 1 as

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an expression host, is the recombinantly produced polypeptide considered to be "naturally-occurring?" If such a polypeptide is not considered to be naturally-occurring, then how does one distinguish this recombinant polypeptide from the corresponding endogenously expressed polypeptide? In the absence of such distinguishing characteristics, it is unclear as to the scope of claimed polypeptides. It is suggested that applicants clarify the meaning of the claims.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[15] The new matter rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, first paragraph, (¶ [7] of the Office action mailed 12/10/2004) is withdrawn in view of the amendment to the claims, specifically, the recited hybridization conditions.

[16] Claims 1-2, 11, 13-14, 24, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 (claim(s) 2 dependent therefrom), 11 (claim(s) 13-14 dependent therefrom), 24, and 26 recite the limitations “wherein said polypeptide has an enzymatic activity at pH 2.5 to 3,” “wherein said polypeptide is stable at 50°C or less,” and “wherein said polypeptide has an approximate molecular weight of about 47 kDa as determined by SDS-PAGE.” MPEP § 2163 states, “when filing an amendment an applicant should show support in the original disclosure for new or amended claims” and “[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description”.

Regarding the limitation, “wherein said polypeptide has an enzymatic activity at pH 2.5 to 3,” applicants refer to p. 47, line 25 to p. 48, line 1 of the specification as supporting the recited limitation (see p. 5, top, of the response filed 5/9/2003), which states, “[a]s a result, it was found that its optimum pH was from 2.5 to 3.0.” This statement specifically refers to the characterization of the A. fumigatus diglycosidase of SEQ ID NO:8. While this disclosure supports a polypeptide of SEQ ID NO:8 having enzymatic activity at pH 2.5 to 3.0, it does not support all polypeptides as encompassed by the claims from microorganisms other than A. fumigatus having enzymatic activity at pH 2.5 to 3.0.

Regarding the limitation, “wherein said polypeptide is stable at 50°C or less,” this limitation was added in the amendment filed 10/30/2002, however, applicants have failed to “show support” for this recited limitation. The examiner acknowledged support

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for this limitation at p. 50, line 2 of the specification (p. 4, top, Office action mailed 1/10/2003). However, it is noted that the disclosure of "stable at 50°C or less" refers to a diglycosidase activity from those microorganisms listed in Table 6 at p. 45 of the specification. While this disclosure supports a polypeptide isolated from those microorganisms listed in Table 6 having diglycosidase activity that is stable at 50°C or less, it does not support a diglycosidase polypeptide from microorganisms not listed in Table 6 that is stable at 50°C or less.

Regarding the limitation, "wherein said polypeptide has an approximate molecular weight of about 47 kDa as determined by SDS-PAGE," applicants refer to p. 47, lines 8-10 of the specification as supporting the recited limitation (p. 7 of the response filed 10/17/2003), which states, "[a]n SDS-PAGE analysis confirmed that the enzyme [SEQ ID NO:8] was purified as a single band of 47 kDa." First, it is noted that, while this disclosure supports an enzyme of SEQ ID NO:8 having a molecular weight of 47 kDa, it does not support a limitation of an enzyme having "an approximate molecular weight of about 47 kDa..." (underline added for emphasis) as recited in the claims. Second, it is noted that the claims encompass diglycosidase polypeptides from microorganisms other than A. fumigatus and the disclosure of "[a]n SDS-PAGE analysis confirmed that the enzyme [SEQ ID NO:8] was purified as a single band of 47 kDa" fails to support diglycosidases other than A. fumigatus diglycosidase of SEQ ID NO:8 having a molecular weight of 47 kDa. It should be noted that, if this limitation is deleted from the claims, a scope of enablement rejection of claims 1-2, 11, 13-14, 24, and 26 may be reinstated.

[17] The written description rejection of claims 1-2, 11, 13-14, 24, and 26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants rely on the Tsuruhami Declaration in support of their position that the genus of claimed or recited polypeptides is described by the instant specification. According to applicants, a skilled artisan would not expect to find substantial structural variation between the “naturally-occurring” diglycosidase of A. fumigatus and the “naturally-occurring” enzymes within the scope of the claims. Applicants argue numerous representative species of the recited polypeptides have been isolated and characterized, referring to Table 6 at p. 45 of the specification. According to applicants, a representative number of species is disclosed “since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicants were in possession of the claimed invention,” referring to Example 9 of the Revised Interim Written Description Guidelines Training Material.

Applicants' argument is not found persuasive. Whether the genus encompasses polypeptides having “substantial structural variation” is not at issue. The issue is whether the single representative species of SEQ ID NO:8 is sufficient to describe the recited genus of “naturally-occurring” polypeptides. The Court of Appeals for the Federal Circuit has held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula [or] chemical name,’ of the claimed subject matter sufficient to

distinguish it from other materials.” UC California v. Eli Lilly, (43 USPQ2d 1398). The CAFC has also held that “A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials” Amgen Inc. v. Chugai Pharmaceutical Co. Ltd. (18 USPQ2d 1016).

In this case, it remains unclear as to how a skilled artisan – in view of the single disclosed representative species of SEQ ID NO:8 – can distinguish the subgenus of polypeptides that are “naturally-occurring” from the larger genus of polypeptides that includes both “naturally-occurring” polypeptides and non-naturally-occurring polypeptides.

Given the lack of description of a representative number of polypeptides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

Conclusion

[18] Status of the claims:

Claims 1-2, 4, 11, 13-14, 22, 24, and 26 are pending.


Claims 4 and 22 appear to be in a condition for allowance.

Claims 1-2, 11, 13-14, 24, and 26 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are

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unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.



DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER